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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,094	02/08/2002	Francisco Javiar Garcia-Ladona	0480/01203	5429

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EXAMINER	
LOCKARD, JON MCCLELLAND	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 10/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,094	GARCIA-LADONA ET AL.	
	Examiner	Art Unit	
	Jon M. Lockard	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 13-29* is/are pending in the application.

4a) Of the above claim(s) *3,8-10 and 13-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-7 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-11 and 13-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Amendment filed 27 July 2005 has been received and entered in full. Claims 1, 4, and 7 have been amended and claim 12 has been cancelled. Therefore, claims 1-11 and 13-29 are pending and claims 1-2, 4-7, and 11 are the subject of this Office Action.

3. Claims 3, 8-10, and 13-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

4. The restriction requirement is still deemed proper and is therefore made FINAL.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections and/or Rejections

6. The objection to the disclosure as set forth at page 4 (¶ 9) of the previous Office Action is withdrawn in view of Applicants' amendments which include a brief description of the drawings (filed 27 July 2005).

7. The objection to claim 12 for encompassing non-elected inventions as set forth at page 4 (¶ 10) in the previous Office Action (mailed 25 January 2005) is moot in view of Applicants cancellation of said claim (filed 27 July 2005).

8. The rejection of claims 1-2 and 4-7 under 35 U.S.C. §112, 2nd Paragraph as set forth at page 5 (¶ 11-14) in the previous Office Action (mailed 25 January 2005) is withdrawn in view of

Applicants' arguments and amendment of claims 1 and 7 which now recite "neuroleptic malignant syndrome" (filed 27 July 2005).

9. The rejection of claims 1-2, 4-7, and 11-12 under 35 U.S.C. §112, 2nd Paragraph as set forth at pages 5-8 (¶ 15-20) in the previous Office Action (mailed 25 January 2005) is withdrawn in view of Applicants' arguments and cancellation of claim 12 (filed 27 July 2005).

10. The rejection of claims 1-2, 4-5, and 12 under 35 U.S.C. §102(b) as being anticipated by Pratt et al. as set forth at page 8 in the previous Office Action (mailed 25 January 2005) is withdrawn in view of Applicants amendment of said claims which disclaim haloperidol frm the homer expression modifying compounds (filed 27 July 2005).

Maintained/ New Objections and/or Rejections

Drawings

11. It is noted at page 9 of the response (filed 27 July 205) that Applicants have submitted a new Figure 1, however, no drawing has been received. Applicants are requested to resubmit the drawing sheet and reminded that each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d).

Claim Rejections - 35 USC § 112, 1st Paragraph (Written Description)

12. Claims 1-2, 4-5, 7, and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

13. The claims are drawn quite broadly to a method treatment comprising administering a composition comprising an effective amount of a homer expression modifying compound other than haloperidol. The claims do not require that the homer expression modifying compound possess any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of compounds that are defined only by a desired effect on homer expression.

14. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is a recitation of a desired effect on homer expression. There is no identification of any particular structure of the compounds, physical and/or chemical properties of the compounds, or methods of making the compounds. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. Additionally, the description of haloperidol, SIB1893, and MPEP is not adequate written description of an entire genus of functionally equivalent compounds that modify homer expression.

15. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was

in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed"* (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116).

16. With the exception of the compounds referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed compounds, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The polypeptide itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

17. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

18. Therefore, only haloperidol, SIB1893, and MPEP, but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claims 1-2, 4-7, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Varney et al. (1999, The Journal of Pharmacology and Experimental Therapeutics. 290:170-181.

22. Varney et al. teach a compound disclosed as SIB-1893, which is also referred to as 2-methyl-6-(2-phenylethynyl)-pyridine (See Abstract, pg 170). Varney et al. also teach teach that SIB-1893 acts on glutamate receptors and is a selective noncompetitive antagonist of human metabotropic glutamate receptor type 5 (mGluR5).

23. Varney et al. are silent with regards to the effect of SIB-1893 on homer expression or action on glial cells, and do not explicitly teach administration of SIB-1893 to a human to treat malignant syndrome or psychosis.

24. First, it is noted that a compound and all of its properties are inseparable; they are one and the same thing (see *In re Papesch*, CCPA 137 USPQ 43; *In re Swinehart and Sfiligoj*, 169 USPQ 226 (CCPA 1971)). Simply stating a new property of the compound of Varney et al. (i.e., modulates homer expression, action on glial cells) does not render the compound of the instant application free of the art. While Varney et al. do not explicitly teach administration of SIB-1893 to a human to treat malignant syndrome or psychosis, they clearly suggest that administration of SIB-1893 may be used to treat psychiatric disorders (See pg 179).

25. Thus, the claimed invention as a whole was *prima facie* obvious over the teachings of the prior art.

Summary

26. No claim is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback**, can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

JML
October 13, 2005

Bridget E. Bunner

BRIDGET BUNNER
PATENT EXAMINER